REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the amendments and remarks herein.

Claims 1-55 are pending in the application. It is noted that the Examiner did not acknowledge the existence of Claim 53, which was added in the Office Action submitted on September 10, 2004. As noted in that document, Claim 53 depends from Claim 52 and recites that the ulcer is a foot ulcer resulting from diabetes-related vasculoneuropathy. Claims 54 and 55 have been added by this amendment. Support for the new claims can be found throughout the specification, and particularly on pages 10 (lines 26-30) and 13 (lines 10-11). Applicant submits that no new matter is introduced by these amendments.

I. Consideration of Previously Submitted Information Disclosure Statements

We note with appreciation that the Examiner has returned initialed copies of the PTO 1449 forms originally submitted by Applicant on October 30, 2001. However, initialed copies of the PTO 1449 forms submitted by Applicant on April 3, 2002, and May 18, 2004, have not been returned to Applicant's representative. Accordingly, a further copy of both sets of PTO 1449 forms is included herewith and Applicants respectfully request consideration of each disclosed document by the Examiner and return of an initialed copy of each form to Applicant.

II. Claim Rejections

Claims 1-52 remain rejected under 35 U.S.C. §103(a) as being unpatentable over the WO 00/02999 Usala reference in view of the Miller article, and further in view of U.S. Pat. No. 5,487,899 to Davis or U.S. Pat. No. 5,059,588 to Pickart et al. Similarly, Claims 1-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,231,881 to Usala in view of the Miller article and either Davis or Pickart. Further, Claims 1-29, 31-42, 46-48, and 50-51 remain rejected under the doctrine of obviousness-type double patenting as being

unpatentable over the claims of U.S. Patent No. 6,261,587 in view of the Miller reference, and in further view of the Davis or Pickart patents.

In response to Applicant's previous arguments, the Examiner has taken the position that the Miller article teaches that an ulcer grows through tissue granulation and reepithelialization and has alleged that the Miller reference suggests numerous agents that can be administered to the ulcer to provide an optimal environment for healing. The Examiner goes on to allege that the Miller reference teaches that antibiotics and growth factors result in the stimulation of granulation of tissue, and that it is well known that granulation of tissue consists of new blood vessel formation, fibroblast activity, and reepithelialization, as evidenced by Davis or Pickart. The Examiner concludes that one of ordinary skill in the art would be motivated by the Miller reference to use the hydrogel matrix of the Usala references of record to treat diabetic foot ulcers because, based on the prior art, "one would expect vascularization to lead to granulation of the tissue and ultimate treatment of the ulcer." Applicant respectfully traverses all of the above rejections, and particularly traverses the statement quoted above.

As an initial point, Applicant notes that the Examiner has not acknowledged Claim 53 added with the previous amendment. As previously argued, the Miller reference, to the extent that it is relevant at all, only suggests the vascular repair treatment relied upon by the Examiner for ischemic ulcers. Claim 53 recites that the ulcer is a foot ulcer resulting from diabetes-related vasculoneuropathy. Since the Miller reference fails to suggest vascular repair as a treatment option for neuropathic ulcers, Applicant respectfully submits that Claim 53 is patentable over the cited combination of references for at least this reason. Thus, Applicant respectfully requests formal notification that Claim 53 is allowable over the cited art.

Applicant also respectfully submits that the Miller reference would not be viewed by one of ordinary skill in the art as providing motivation to use the hydrogel matrix described in the Usala references in the treatment of a diabetic ulcer. While the Examiner is correct that page 761 of the Miller reference contains a single sentence that addresses granulation tissue and reepithelialization, the reference only mentions those effects as a consequence of surgical debridement of necrotic tissue. This specific sentence referred to on page 761 by the Examiner states that "[n]ecrotic tissue and callus must be completely excised to provide a clean ulcer base

in preparation for a granulation tissue and reepithelialization." The only motivation that this sentence provides to one skilled in the art is to utilize tissue debridement as a means for preparing an ulcer for granulation tissue and reepithelialization. There is no mention on page 761 of any other ulcer treatment that is designed to have any effect on granulation tissue or reepithelialization. Thus, the teachings on page 761 are irrelevant to the presently claimed invention.

The teachings relied upon by the Examiner on page 762 are likewise irrelevant to the present invention. The Examiner states that the Miller reference teaches that "antibiotics and growth factors" result in stimulation of granulation of tissue. However, this is not entirely accurate. Page 762 of the Miller reference teaches that a moist environment promotes reepithelialization. For that reason, the Miller reference teaches the use of moist saline dressings, the use of antibiotics to prevent desiccation of the wound base, and benzoyl peroxide to promote a moist antiseptic wound bed. The Miller reference focuses on treatments designed to keep the wound moist and never states that antibiotics directly lead to reepithelialization or granulation tissue. Page 762 of Miller does state that benzoyl peroxide "might" stimulate granulation tissue, but such an ambivalent statement can hardly be expected to motivate one of ordinary skill in the art in any way meaningful to the present invention. The only teaching in Miller regarding growth factors is a single sentence that states that such factors attract fibroblasts and other cells involved in the early phases of wound healing. The reference does not state that growth factors lead to tissue granulation. Thus, it is respectfully submitted that the Examiner appears to have described the teachings of the Miller reference in overly broad terms. There is clearly no express teaching in the Miller reference that would suggest that an agent that increases vascularization would lead to granulation of tissue and ultimate treatment of an ulcer. In fact, the Miller reference fails to suggest or describe any ulcer treatments that lead to vascularization and does nothing to indicate that such treatments would be helpful.

The Examiner goes on to rely upon either the Davis or Pickart patents as teaching that granulation of tissue consists of new blood vessel formation, fibroblast activity, and reepithelialization. However, these teachings fail to address the deficiencies of the Miller reference. Davis and Pickart merely describe the cascade of events involved in wound healing

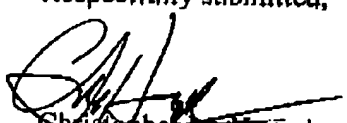
and note that formation of blood vessels is only one aspect of granulation tissue formation. The Davis and Pickart references suffer from the same deficiency as Miller. There is nothing in either Davis or Pickart to suggest that stimulation of microvasculature by itself will stimulate wound healing. As noted in both references, granulation tissue formation involves other processes, such as fibroblast activity and reepithelialization. There is no suggestion in either reference that stimulation of blood vessel formation alone will automatically trigger the remaining wound healing processes (i.e., fibroblast activity or reepithelialization) that are necessary for tissue granulation. Thus, the art of record simply does not support the Examiner's statement that vascularization would be expected to lead to tissue granulation.

In closing, Applicant again emphasizes that none of the references of record teach or suggest that improving microvasculature would necessarily result in stimulation of the wound healing process, particularly in the context of chronic ulcer treatment. The Miller reference does not even mention microvasculature formation at all. In light of these deficiencies of the cited art, Applicant respectfully requests reconsideration and withdrawal of all rejections noted above.

It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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